

Notice of Allowability

Application No.

10/821,573

Examiner

Sheridan L. Swope

Applicant(s)

GILBERT ET AL.

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to August 22, 2006.
2. ☒ The allowed claim(s) is/are 43,44 and 46.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date <u>0404;0806</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

Art Unit: 1652

DETAILED ACTION

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1652.

Applicant's response, on August 22, 2006, to the Action on the Merits of this case mailed April 20, 2006, is acknowledged. It is acknowledged that Applicants have amended Claims 43 and 45. It is unclear whether Claim 45 is pending because the claims list indicates that it has been canceled, but Claim 45 has been amended and is stated as pending in the conclusion section of Applicants' response. For purposes of examination, it is assumed that Claim 45 is pending. Therefore, Claims 43-46 are pending and are hereby reconsidered.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Double Patenting

Rejection of Claims 43-46 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 13-20 and 43-45 of US 10/303,161 as well as Claims 43-46 and 51 of US 10/821,604, for the reasons explained in the prior action, is withdrawn. A terminal disclaimer has been filed over 10/303,161. In additions, Applicants have stated that a terminal disclaimer will be filed over 10/821,604, if said application becomes allowable.

Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to Applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Specification

Delete all URLs, as follows.

On page 4, parag 2: ~~-(www.sanger.ac.uk/Projects/- C_jejuni/-).~~

On page 5, parag 1: ~~-(www.cris.com/.about.ketchup/genedoc.sh- tml)-.~~

On page 15, parag 2: ~~-(www.ncbi.nlm.nih.gov/-).~~

On page 53, parag 3: ~~-(www.sanger.ac.uk/ Projects /C_jejuni/-).~~

On page 56, parag 1: ~~-(www.sanger.ac.uk/Projects/C_jejuni/-).~~

Claims

Cancel Claim 45.

Authorization for this examiner's amendment was given in a telephone interview with Beth Kelly's assistant, Kevin Bastian, on November 13, 2006.

Allowable Subject Matter

Claims 43, 44, and 46 are allowed.

The following is an examiner's statement of reasons for allowance:

All elected claims, Claims 43, 44, and 46, are limited to an isolated or recombinant polypeptide having α -2,3-sialyltransferase activity, wherein the polypeptide is encoded by a nucleic acid molecule that can be generated by PCR using *Campylobacter* DNA and the primers

Art Unit: 1652

set forth by SEQ ID NO: 46 and 47. The elected invention is free of the art. The utility of the recited polypeptide, as having α -2,3-sialyltransferase activity, is credible based on the following. Applicants used the primers set forth by SEQ ID NO: 46 and 47 to generate a polynucleotide, ORF 7a, from *Campylobacter* strain OH4384 (Table 2), which encodes the polypeptide set forth by SEQ ID NO: 2 (sequence listing). Said polypeptide, also denoted as cstII, was analyzed by enzymatic assay and shown to have α -2,3-sialyltransferase activity (Table 5). It would not be undue experimentation for the skilled artisan to use the recited primers in a PCR to generate, from other *Campylobacter* strains, polynucleotides encoding additional α -2,3-sialyltransferase proteins and to isolate said proteins from transfected host cells. α -2,3-sialyltransferases catalyze the transfer of a first sialic acid from the donor to the acceptor in an α 2,3 linkage. Subsequent processing by other sialyltransferases results in an α 2,8 linkage, a structure often found in gangliosides. Thus, the recited polypeptides have real-world use in the production of gangliosides. Therefore, the recited invention has a specific and substantial patentable utility.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

Art Unit: 1652

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sheridan Lee Swope, Ph.D.
Art Unit 1656

A handwritten signature in black ink, appearing to read 'Swope', with a stylized, flowing script.

SHERIDAN SWOPE, PH.D.
PRIMARY EXAMINER